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DOI:
10.1016/j.eujim.2016.11.017

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Document Version
Peer reviewed version

Citation for published version (Harvard):
Lee, RT, Kingstone, T, Roberts, L, Edwards, S, Soundy, A, Shah, P, Haque, S & Singh, S 2016, 'A pragmatic randomised controlled trial of healing therapy in a gastroenterology outpatient setting', *European Journal of Integrative Medicine*. https://doi.org/10.1016/j.eujim.2016.11.017

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Checked 12/12/2016

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Download date: 05. May. 2023

Research paper

A pragmatic randomised controlled trial of healing therapy in a gastroenterology outpatient setting

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Abstract
IntroductionTo determine the benefits of healing therapy (spiritual healing) as an adjunct to conventional management in irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).
Methods200 outpatients with IBS or IBD were randomised to either conventional treatment (control) or conventional plus 5five sessions of healing therapy (intervention). After 12 weeks controls also had healing therapy. Outcomes used were, the Measure Yourself Medical Outcomes Profile (MYMOP). IBS-QOL, IBDQ, and symptom measures.
ResultsThere was a significant improvement in the MYMOP score at week 6 ($p < 0.001$) which was maintained to week 12 ($p < 0.001$) and 24 ($p < 0.001$). Improvements in MYMOP were significantly greater in the intervention group at both 6 ($p < 0.001$) and 12 weeks ($p < 0.001$) with effect sizes of 0.7 (95% CI: 0.4–1.1) and 0.8 (95% CI: 0.4–1.2). Condition-specific data for IBS showed that most QoL dimensions had a significant minimum 10-point score improvement at 6 and 12 weeks. The overall score improvement was 12.9 units at week 6 ($p < 0.001$), 12.4 units at week 12 ($p < 0.001$) and 13.8 units at week 24 ($p < 0.001$). In IBD there was also similar score improvement, but only up to week 12 were there associations of improved social and bowel functions ($p < 0.001$, respectively). Between group differences were identified for QoL scores in IBS at both week 6 ($p < 0.001$) and 12 ($p < 0.001$) but only for week 12 ($p < 0.001$) in the IBD group.
ConclusionsThe addition of healing therapy to conventional treatment was associated with improvement in symptoms and QoL in IBS, and to a lesser extent in IBD.
Abbreviations
IBSirritable bowel syndromeIBD
inflammatory bowel disease
Keywords
Complementary therapyHealingSpiritual healingReikiHealing touchIrritable bowel syndromeUlcerative CcolitisCrohn’s disease
Inflammatory bowel disease
1
Introduction
Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD) are both gastrointestinal disorders of unknown aetiology that significantly reduce quality of life (QoL), impacting on several aspects of personal, physical, psychological, mobility, social and employment status (IBS [1–5]) (IBD [6–8]) with high demands on healthcare resources [9,10]. IBS is considered a functional disorder with symptoms of abdominal pain or discomfort with alternating diarrhoea and constipation or a predominance of either one. It has a community prevalence of 10.5–11.5% [1,5], accounting for 30% of “gut problems” presented in primary care [11]. IBD includes ulcerative colitis (UC) and Crohn’s disease (CD) with a UK prevalence rate of 0.25–0.3% for UC and 0.15–0.375% for CD [12,13]. Both are associated with abdominal pain and diarrhoea marked by episodes of flare-up and periods of remission resulting in long term morbidity. Furthermore, in UC there is diffuse mucosal inflammation of the colon along with bloody diarrhoea while CD is characterised by weight loss and patchy inflammation of the intestinal mucosa [14]. There is no universally effective treatment for IBS [15] or IBD [14,16,17] and it varies between pharmacological drugs, dietary advice and lifestyle changes, but also surgical treatment in around half of CD patients. Complementary and Alternative Medicine (CAM) is a holistic person-centred approach to patient care prevalent in the general population [18–20]. It covers a wide range of therapies e.g. acupuncture, massage and herbal medicine, and is accessed by around 10% of the UK adult population [21] typically to supplement conventional care [22]. Amongst patients with gastrointestinal complaints it is estimated that 50% commonly use CAM [23,24]. Around 90% of CAM provision in the UK is purchased privately, the estimated value of which was £1.6 billion in 2000 [18]; which excludes NHS and charity-funded CAM usage [25]. Smallwood’s report into the cost effectiveness of CAM within the NHS concluded that CAM should be targeted at the effectiveness gaps of conventional health care [25].
Healing therapy forms part of the energy therapy sub-group of CAM. Energy therapies are based upon the putative concept that humans are permeated by subtle energy fields; imbalances in an individual’s energy field may occur which can be detrimental for health [26]. Some methods of healing have a long history in their country of origin,

eg spiritual healing in the UK and reiki in Japan. Others have been developed relatively recently, eg Therapeutic Touch in the USA. Therapeutic touch is described as "The conscious use of the hands to direct or modulate, for therapeutic purposes, selected nonphysical human energies that activate the physical body" [27]. Because of preliminary experience spiritual healing was the form of healing therapy evaluated in this study. Spiritual Healing is described as the channelling of energy through the healer to the patient. In this form of healing therapy, the therapist need not know of the patient's symptoms as there is no conscious direction of therapy. The aim of the therapy is to facilitate self-healing within the patient.

To the best of the authors' knowledge, and an electronic search of medical literature, there have been no previous clinical trials of healing therapy in either IBS or IBD. There is evidence of healing therapy stimulating growth of human osteoblastic cells and inducing differentiation and mineralization [28]; and being beneficial in pain relief [29], osteoarthritis of the knee [30], burn patients [31], and fibromyalgia [32]. Other studies on diabetic neuropathy [33] and asthma [34] did not show any benefit, and a Cochrane review on wound healing [35] was inconclusive. These variable results suggest the need to evaluate its efficacy in different patient groups before adopting it as a therapeutic intervention. This study aimed to determine the benefits of healing therapy as an adjunct to conventional management of individuals with IBS and IBD.

2 METHODSethods

2.1 Trial design

This study was a randomised controlled trial of healing therapy for people with a clinical diagnosis of IBS or IBD. It was pragmatic using a two-armed design, comparing the effectiveness of five sessions of healing therapy as an adjunct to conventional treatment against a waiting list control receiving conventional treatment only. One change regarding the inclusion of CD patients was made after the original protocol (http://www.isrctn.com/ISRCTN13039379) was submitted. The allocation ratio was 1:1 (waiting-list: intervention); the computer generated blocked randomisation list (block size = 6) was stratified by disease type (IBS and IBD) to ensure equal allocation to each arm. Allocation was concealed and randomisation was carried out remotely via telephone between the hospital based research assistant and the list controller (co-investigator) once eligibility had been confirmed and consent achieved. Randomisation took place after informed consent was achieved and baseline questionnaires had been completed in the presence of the participant who was then informed immediately of the outcome. Due to the nature of the intervention no blinding was possible. At the end of 12 weeks the waiting list control group also received treatment. This allowed all participants to receive the intervention. This trial was approved by The Black Country Research Ethics Committee, West Midlands, UK (identifier 10/H1202/36), and informed written consent was obtained by all participants. Formal between-group comparisons are those undertaken at week 6 and 12, although we report data from week 24 both to enable the longer-term impact of the intervention to be assessed in the intervention group and impact between week 12 and 24 in the waiting list control group.

The trial was conducted at two Birmingham (UK) study sites located within the Heart of England NHS Foundation Trust. Participants were recruited from gastroenterology outpatient's clinics either through routine appointments or by postal invitation following retrieval from the patient database. Initially, eligibility criteria were an age 18 years and over, having attended clinic in the previous 12 months with a clinical diagnosis of IBS (confirmed by ROME II criteria) or with a clinician diagnosis of Ulcerative Colitis. In month 8 due to low recruitment rates this was extended to include individuals with a clinician diagnosis of Crohn's Disease to supplement the IBD group. Exclusion criteria included: having received healing therapy (including reiki) in the last 6 months; being unable to provide fully informed consent; being unable to self complete outcome questionnaires; those engaged in or having completed another clinical trial in the previous 8 weeks; and pregnant women.

2.2 The intervention

The intervention consisted of 5 weekly sessions of 30 minutes of healing therapy delivered by therapists in addition to usual clinical management. Participants who failed to attend an appointment were offered a replacement session. For uniformity of method, healing therapy was delivered by healers trained in Spiritual Healing by, and members of The Healing Trust [36] in a private consultation room within the hospital. The Healing Trust was established in 1954. Members undergo a minimum of 2 years of

nationally standardised training and mentoring by a qualified member, testimonials and final panel assessment. Participants received healing therapy fully clothed on a clinic couch or seated in a chair with back support, depending on comfort and/or disability. Therapy was not standardised but was administered as per training, each session beginning by the healer lightly placing their hands on the patient's shoulders. Thereafter the healer's hands are maintained a short distance (10–12 in.) from the participant's body gradually working towards the feet and placing the hands there. With verbal consent, some healers worked with light touch on the shoulders, feet, arms and legs for short periods of time. Depending on the therapist, music may have been played to promote a relaxed atmosphere during the session.

2.3

Data collection

A selection of validated self-report outcome measures were used, with outcomes recorded at week 0 (baseline), 6, 12, and 24. Qualitative data were also collected to ensure the full range of potential experiences were determinable, published in a separate paper [37]. The primary outcome measure, the Measure Yourself Medical Outcome Profile (MYMOP) [38], is a validated patient-centred problem-specific instrument specifically developed for use in the study of complementary and alternative medicine. This individualised measure has demonstrated greater responsiveness to change than the SF36 Physical Component Summary [39] and requires patients to identify the two most problematic symptoms', and an activity restricted by health problems. These three items and the patient's general well-being are scored by the patient on seven-point scales for experiences over the preceding week. Collectively they generate a MYMOP profile (composite mean score), wherein lower scores indicate less severity/impact of the condition. The primary outcome of the trial was pre-specified as change in MYMOP score and primary analysis compared change in score for those in the intervention versus waiting list control groups.

The secondary outcome measures included disease specific QoL and symptom severity measures. QoL was evaluated using validated tools; the IBS-QOL questionnaire [40] and IBDQoL measure (IBDQ) [41] assessing health related QoL in people with IBS and IBD respectively. Symptoms were evaluated using the Birmingham IBS Symptom questionnaire [42], Simple Clinical Colitis Activity Index (SCCAI) [43] and a modified version of the Harvey-Bradshaw Index [44] capturing symptom severity in IBS, UC and CD respectively. The total scores for measures, and for dimensions within measures, were achieved by summing the constituent items except for the MYMOP which produced a mean as an individual's profile score. In the case of the QoL measures (IBS-QoL and IBDQ), scores for dimensions and for totals were converted to scores out of 100, where a high score indicated better QoL. The IBS symptom severity measure produced dimension scores for pain (0–25 scale), constipation (0–15) and diarrhoea (0–15), and also a composite total (0–55 scale), where lower scores indicated lesser severity. The UC symptom severity measure produced a single total score from 0– to 19, where low scores indicated lesser severity. Similarly, the CD symptom severity measure produced a total score for which there was no higher bound, only low scores indicated lesser severity (a score of 13 was anticipated to be around the top of the scale).

Follow-up data were collected via postal correspondence and incomplete responses were included for all available data. Where data are missing this is due to failed response or partial response from the patient.

2.4

Sampling

The sample size was determined based on power calculations regarding the primary outcome (MYMOP). Considerations were also afforded to numbers of participants with IBS and IBD in terms of final sample size estimates. Eighty-five individuals in each arm would enable identification of a 0.6 unit difference in MYMOP score change at the 5% significance level with 80% power – based on assumptions from a prior trial of healing therapy [45]. Assuming around a 10% loss to follow up, we determined to recruit 100 participants in each arm. Of the overall target of 200, 50% were targeted from the IBS patient group with the remaining 50% comprising of UC and CD participants. This was done to preserve power in secondary disease-specific analyses although it was acknowledged that small numbers in sub groups would limit the ability to detect small or moderate effects.

2.5

Statistical analysis procedures

Baseline characteristics were summarised using descriptive statistics. Analysis of all outcome measures was undertaken on an Intention-to-Treat (ITT) basis. Per protocol analysis (PPA) was undertaken comparing waiting list controls with only those intervention group participants who attended all 5 sessions of healing therapy (78%). Analysis of the primary outcome (change in MYMOP score) was undertaken at a combined patient group level, regardless of disease type. Additional sub-group analyses split data by disease type. Comparative analyses of each of the outcome measures were conducted using univariate statistics calculated in SPSS version 19. In the case of MYMOP univariate analyses were non-parametric due to non-normally distributed data. Comparisons of total scores from respective measures were pre-specified as demonstrating difference at a significance level of $p < 0.01$; however, for analysis of sub-scale or dimension scores a stricter significance level of $p < 0.005$ was specified due to multiple testing.

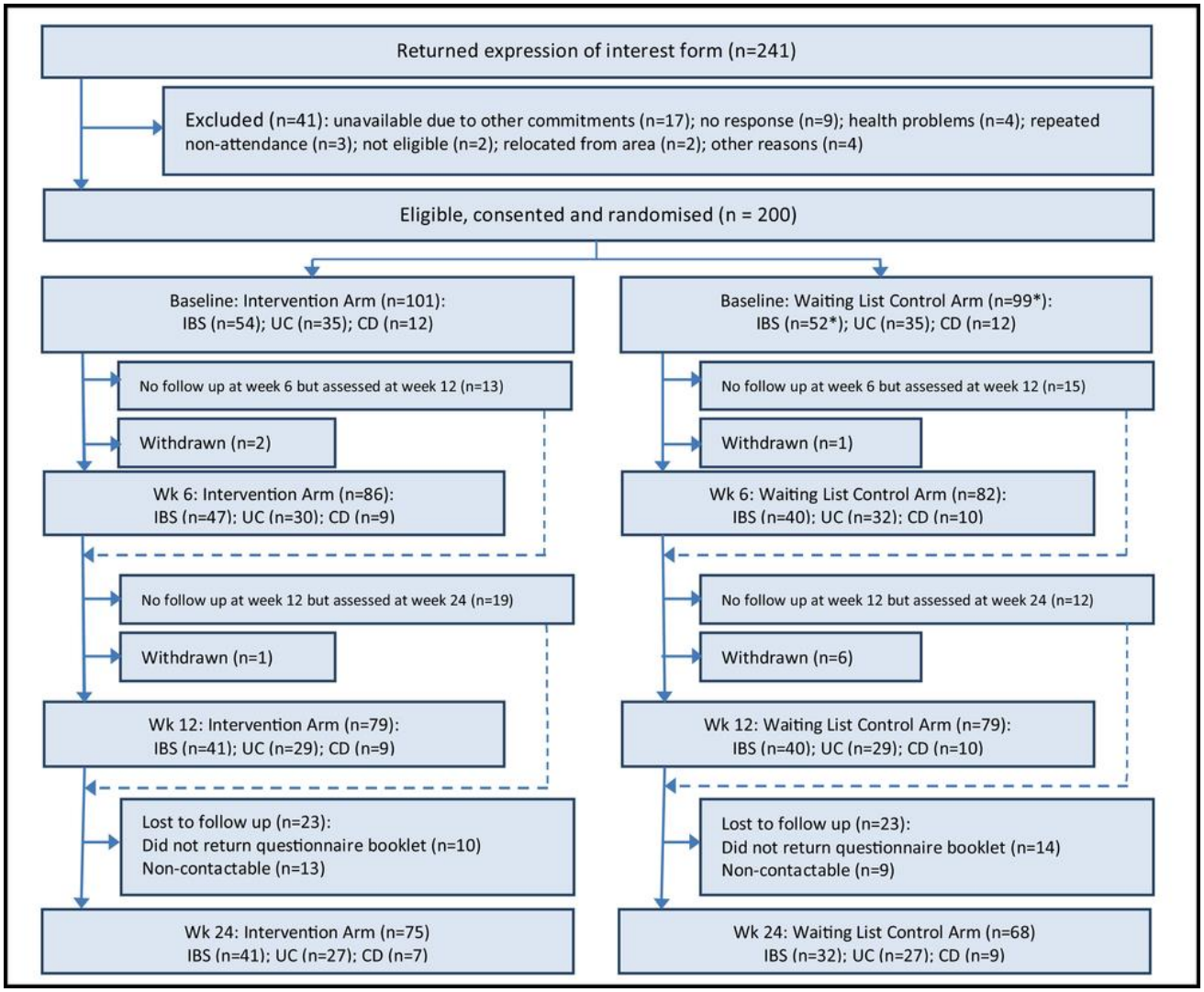
A two level hierarchical model with random intercept was created for each of the outcome variables (i.e. a patient specific regression line where each patient has his/her own regression line as opposed to a single regression line to represent all the patients) adjusting for age, gender and years since diagnosis. Difference-in-differences analysis was conducted using this model in the statistical package STATA version 12 in order to compare differences between baseline and 6 and 12 weeks' outcome scores between the groups.

Imputations for missing data were undertaken on a case-by-case basis. A maximum of three missing values were permissible from any one outcome measure; where more than three values were missing from a specific measure, the total score was removed from analysis. A maximum of two missing values were permissible from any one dimension or sub-scale (only one allowed for dimensions of three or fewer items), where more than two items were missing these dimensions were removed from analysis. When the item(s) was (were) missing from an outcome measure a mean imputation was used i.e. a mean score from the completed items or from the completed dimension items was calculated and inputted.

3

RESULTSesults

In total, 241 patients expressed an interest in participating in this trial, from September 2010 to February 2012. A total of 200 (83%) met the eligibility criteria, consented to take part and were randomised (Fig. 1). Of these, 168 (84%) completed 6 week follow-up measures, 158 (79%) completed 12 week follow-up measures, and 143 (72%) completed the 24 week follow-up measures. The attrition rate was similar across study arms; reasons for attrition are detailed in Fig. 1. Data collection was completed in August 2012.


Returned expression of interest form (n=241)
Excluded (n=41): unavailable due to other commitments (n=17); no response (n=9); health problems (n=4); repeated non-attendance (n=3); not eligible (n=2); relocated from area (n=2); other reasons (n=4)
Eligible, consented and randomised (n = 200)
Baseline: Intervention Arm (n=101): IBS (n=54); UC (n=35); CD (n=12)
Baseline: Waiting List Control Arm (n=99*): IBS (n=52*); UC (n=35); CD (n=12)
No follow up at week 6 but assessed at week 12 (n=13)
Withdrawn (n=2)
No follow up at week 6 but assessed at week 12 (n=15)
Withdrawn (n=1)
Wk 6: Intervention Arm (n=86): IBS (n=47); UC (n=30); CD (n=9)
Wk 6: Waiting List Control Arm (n=82): IBS (n=40); UC (n=32); CD (n=10)
No follow up at week 12 but assessed at week 24 (n=19)
Withdrawn (n=1)
No follow up at week 12 but assessed at week 24 (n=12)
Withdrawn (n=6)
Wk 12: Intervention Arm (n=79): IBS (n=41); UC (n=29); CD (n=9)
Wk 12: Waiting List Control Arm (n=79): IBS (n=40); UC (n=29); CD (n=10)
Lost to follow up (n=23): Did not return questionnaire booklet (n=10) Non-contactable (n=13)
Lost to follow up (n=23): Did not return questionnaire booklet (n=14) Non-contactable (n=9)
Wk 24: Intervention Arm (n=75) IBS (n=41); UC (n=27); CD (n=7)
Wk 24: Waiting List Control Arm (n=68) IBS (n=32); UC (n=27); CD (n=9)
Fig. 1

Flow chart of participants. Reasons for withdrawals from trial included the following −– serious co-morbid health problem experienced prior to intervention (n = 3); other commitments (n = 4); contravened protocol (sought therapy outside of trial) (n = 1); felt well so did not consider benefit could be gained (n = 1); change in circumstance (n = 1). *Disclosure of concurrent trial participation −– deemed to be protocol breach and baseline data not considered in analysis.
Fig. 1

Table 1 presents baseline characteristics of the study participants. Overall, participants had a median age of 46 (IQR 33.0–62.0), were predominantly female (71%) and non-smokers (87%), with only a marginally healthy median BMI of 24.0 (IQR 21.0–27.7), and a diagnosed on average 5 years previously (IQR 1.5 years–10 years). The randomised groups were similar on entry to the trial. Only one serious adverse event was recorded during the study period (a TIA) but this was in the context of an ongoing history of such events and was not deemed to be related to participation. Although detailed data were not collected on disease history, given the recruitment context of a secondary care service, all patients, including those with IBS, have a history of disease states which could not be managed in a primary care setting.

Table 1
Baseline characteristics of the participants.
Table 1

Characteristics	Intervention arm (n = 101)	Control arm (n = 98)	Total (n = 199)
Diagnosis			
IBS	54 (53.5%)	51 (52.0%)	105 (52.8%)
Ulcerative Colitis	35 (34.7%)	35 (35.7%)	70 (35.2%)
Crohn's Disease	12 (11.9%)	12 (12.2%)	24 (12.1%)
Age (yrs)	44.0 (33.0–60.5)	48.5 (34.0–64.0)	46.0 (33.0–62.0)
Sex (female)	73 (72.3%)	69 (70.4%)	142 (71.4%)
BMI (weight kg/height m2)	24.8 (22.6–29.3)	23.9 (21.1–27.8)	24.4 (21.0–27.7)
Current smoker	15 (14.9%)	11 (11.2%)	26 (13.1%)
Drinks alcohol	60 (59.4%)	57 (58.2%)	117 (58.8%)
Employed (part or full time)	61 (60.4%)	56 (57.1%)	117 (58.8%)
Length of time since diagnosis (years)	4.5 (1.5–10.0)	6.0 (2.0–10.0)	5.0 (1.5–10.0)
No. of medications (Prescription or OTC)	2.0 (1.0–4.0)	2.0 (1.0–4.0)	2.0 (1.0-−4.0)

Values are numbers (percentages) or medians (Interquartile ranges) due to non-normal distributions. OTC = Over the counter.

All available data contributed to analyses. Of those that were randomised to the intervention arm, 79 (78%) attended all 5 sessions of healing therapy and were included in PPA; a further 12 attended 4 sessions. Two participants failed to attend any sessions. Treatment was not yet completed at 6 weeks for 42% of participants.

Baseline MYMOP scores are provided in Table 2, QoL scores are provided in Tables 3 and 4 for IBS and IBD respectively, and symptom severity scores by disease group are provided in Table 5. Baseline scores were generally comparable between groups – differences were noted in QoL dimension-level scores between randomisation groups but overall scores did not exhibit such differences.

Table 2
MYMOP scores at baseline and 6-, 12-, and 24 weeks.
Table 2

	Symptom 1		Symptom 2		Activity		Wellbeing		Profile	
	C	I	C	I	C	I	C	I	C	I
Baseline Median (IQR)	4 (3–5)	4 (3–5)	4 (3–5)	4 (3–5)	4 (3–5)	4 (3–5)	4 (3–5)	3 (3–4)	4.25 (3.25–4.75)	4.00 (3.00–4.50)
6 weeks Median (IQR)	4 (3–5)	3 (2–4)	4 (3–5)	3 (2–4)	4 (2–5)	3 (1–4)	4 (3–5)	3 (2–4)	3.80 (2.80–4.58)	2.60 (1.73–3.58)
p-value*	0.001		<0.001		<0.001		<0.001		<0.001	
p-value**	0.374	<0.001	0.765	<0.001	0.009	<0.001	0.793	0.002	0.318	0.001
12 weeks Median (IQR)	4 (3–5)	2 (1–4)	4 (2–5)	2 (1–4)	4 (3–5)	2 (1–4)	4 (3–4)	3 (1–4)	3.55 (3.00–4.35)	2.35 (1.30–3.85)
p-value*	<0.001		<0.001		0.001		0.007		<0.001	
p-value**	0.471	<0.001	0.159	<0.001	0.006	<0.001	0.796	0.298	0.324	<0.001
Waiting list control group eligible for intervention at this point (post 12 week)										
24 weeks Median (IQR)	3 (2–4)	3 (1–4)	3 (2–4)	3 (2–4)	2 (1–4)	3 (1–4)	3 (2–4)	3 (2–4)	2.80 (1.78–3.80)	2.75 (1.50–4.00)
P-valueb	0.001	0.001	<0.001	0.001	<0.001	0.001	0.016	0.395	<0.001	0.002

C = (Waiting List) Control Arm. I = Intervention. For maximum n values at baseline and follow-up please refer to Fig. 1. A decline in MYMOP scores indicates improvement in condition. Reports comparisons of ITT analyses only.
*Univariate (between-group comparison – Wilcoxon Mann-Whitney).
**Univariate (within-group comparison to baseline- Wilcoxon signed rank). 95% Confidence Interval.

Table 3
MYMOP Profile Scores according to disease type irritable bowel syndrome (IBS) or inflammatory bowel disease (IBD).
Table 3

	IBS		IBD		Overall	
	MYMOP profile		MYMOP profile		MYMOP profile	
	C	I	C	I	C	I
Baseline median	4.50	4.38	3.75	3.25	4.25	4.00
IQR	4.00–5.25	3.69–5.00	1.50–4.50	2.33–4.25	3.25–4.75	3.00–4.50
6 weeks median	4.20	3.20	3.25	2.00	3.80	2.60
IQR	3.30–4.80	2.25–3.80	2.38–4.23	1.30–3.50	2.80–4.58	1.73–3.58
(p-value) within	0.015	<0.001	0.372	0.016	0.318	<0.001
(p-value) between		<0.001		0.015		<0.001
12 weeks median	3.80	2.90	3.30	1.80	3.55	2.35
IQR	3.30–4.80	1.80–4.00	2.70–4.58	1.00–3.78	3.00–4.35	1.30–3.85
(p-value) within	0.001	0.000	0.094	0.022	0.324	<0.001
(p-value) between		0.005		0.002		<0.001
24 weeks median	3.00	3.13	2.30	2.30	2.80	2.75
IQR	2.25–4.40	2.08–4.45	1.50–3.30	0.30–3.80	1.78–3.80	1.50–4.00
(p-value) within	<0.001	0.007	0.049	0.09	<0.001	0.002

C = (Waiting List) Control Arm. I = Intervention. A decline in MYMOP scores indicates improvement in condition. Reports comparisons of ITT analyses only. Control Group received Intervention also after week 12.
Univariate (between-group comparison – Wilcoxon Mann-Whitney).Univariate (within-group comparison to baseline- Wilcoxon signed rank).95% Confidence Interval.

Table 4
Irritable Bowel Syndrome Quality of Life scores at baseline and 6-, 12-, and 24 weeks.
Table 4

	Overall		Dysphoria		Interference with activity		Body image		Health worry		Food avoidance		Social reaction		Sexual functioning		Relationships	
	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I
Baseline Mean (SE)	40.5 (2.6)	45.5 (3.0)	34.7 (2.9)	39.0 (3.7)	37.2 (3.1)	42.9 (3.5)	47.3 (3.9)	53.4 (3.9)	42.3 (3.0)	48.8 (3.0)	24.5 (3.1)	26.8 (3.6)	45.5 (3.7)	50.6 (3.7)	52.4 (5.0)	57.7 (4.8)	55.1 (3.9)	60.3 (3.4)
6 weeks Mean (SE)	43.0 (3.1)	59.4 (3.3)	40.9 (3.6)	57.3 (3.9)	40.2 (3.8)	57.8 (4.0)	49.0 (3.9)	62.1 (4.1)	47.1 (4.1)	59.4 (3.4)	22.5 (3.4)	39.3 (4.2)	45.0 (4.0)	62.8 (3.7)	50.7 (5.5)	69.5 (4.8)	58.7 (4.1)	71.3 (3.2)
Change from baseline to 6weeks Mean (SE)	3.1 (1.7)	12.9 (2.2)	6.6 (2.3)	17.3 (3.3)	3.3 (2.4)	13.3 (2.6)	2.6 (2.5)	8.3 (2.7)	5.8 (2.4)	10.0 (3.0)	−0.2 (2.2)	12.3 (3.1)	1.4 (2.6)	9.9 (2.8)	2.1 (3.0)	10.4 (3.7)	3.7 (3.3)	10.3 (2.6)
P-value*	0.001		0.003		0.002		0.023		0.016		0.003		0.002		0.012		0.017	
Between group difference(95% CI)	7.2–25.5		5.7–27.1		6.5–28.6		1.8–24.4		2.4–22.3		5.8–27.8		7.0–28.6		4.2–33.3		2.3–22.7	
12 weeks Mean (SE)	47.7 (2.9)	60.0 (3.9)	45.5 (3.5)	60.9 (4.6)	43.3 (3.4)	55.8 (4.0)	50.7 (3.6)	63.3 (4.2)	51.5 (3.6)	60.5 (4.3)	29.8 (3.8)	40.4 (4.6)	50.2 (4.0)	63.0 (4.1)	53.9 (5.3)	69.6 (5.2)	64.6 (3.6)	70.8 (3.8)
Change from baseline to 12weeks Mean (SE)	5.1 (2.0)	12.4 (2.7)	8.6 (2.7)	18.3 (3.5)	4.6 (2.2)	11.4 (2.8)	1.3 (2.7)	6.4 (2.9)	7.5 (2.8)	11.1 (3.5)	4.4 (3.0)	11.4 (4.0)	3.0 (3.0)	10.8 (2.9)	4.4 (3.7)	12.5 (3.7)	6.0 (3.1)	6.7 (3.1)
P-value*	0.013		0.009		0.021		0.026		0.112		0.076		0.027		0.039		0.234	
95% CI	2.7–21.9		4.0–26.9		1.9–22.9		1.6–23.6		−2.2 to 20.2		−1.1 to 22.5		1.5–24.2		0.8–30.5		−4.1 to 16.6	
Waiting list control group eligible for intervention at this point (post 12 week)																		
24 weeks Mean (SE)	52.6 (4.2)	62.8 (3.8)	51.8 (4.7)	64.5 (4.5)	49.6 (4.7)	57.8 (4.4)	53.9 (4.7)	63.6 (4.0)	57.0 (4.6)	64.6 (4.0)	36.7 (4.4)	42.9 (4.7)	54.7 (4.9)	67.8 (4.3)	54.9 (6.1)	70.3 (5.2)	63.3 (4.5)	76.2 (3.5)
Change from baseline to 24weeks Mean (SE)	10.1 (2.5)	13.8 (2.8)	15.0 (3.5)	21.1 (3.8)	11.7 (3.0)	12.2 (2.9)	5.9 (2.8)	4.8 (2.9)	11.5 (2.7)	13.6 (3.2)	10.7 (3.8)	13.5 (3.3)	7.6 (3.5)	13.7 (3.8)	10.3 (3.9)	14.2 (4.8)	4.2 (2.5)	11.3 (2.7)

C = (Waiting List) Control Arm. I = Intervention. For maximum n values at baseline and follow-up please refer to Fig. 1. Outcome and dimension scores have been converted to scores out of 100. A high score denotes higher QoL rating. Positive changes in values between time points indicate an improvement in QoL; Changes calculated using baseline data from only those cases that provided follow-up data. Table reports comparisons of ITT analyses only.
*Univariate (between-group comparison) with 95% CI indicating the between group difference in change.

Table 5
IBD Quality of Life outcome scores at baseline and 6-, 12-, and 24 weeks.
Table 5

	Overall		Emotional function		Bowel Function I		Bowel Function II		Social Function		Systemic Function	
	C	I	C	I	C	I	C	I	C	I	C	I
Baseline Mean (SE)	63.9 (2.9)	62.3 (3.2)	65.2 (2.6)	63.9 (3.1)	61.6 (3.4)	60.3 (4.1)	62.4 (4.0)	56.4 (3.8)	73.9 (3.5)	74.5 (3.8)	51.9 (4.1)	46.8 (4.0)
6 weeks Mean (SE)	66.5 (3.0)	72.0 (3.5)	67.9 (2.6)	74.6 (3.1)	62.1 (3.9)	68.7 (4.4)	61.4 (4.1)	64.5 (4.4)	78.9 (3.5)	84.6 (3.7)	53.7 (4.3)	57.8 (4.4)
Change from baseline to 6 weeks Mean (SE)	1.7 (1.2)	7.0 (2.5)	1.8 (1.3)	7.5 (2.4)	−0.8 (2.3)	6.1 (3.4)	−1.5 (1.8)	7.5 (3.9)	3.9 (2.3)	5.5 (2.4)	0.7 (2.5)	9.1 (4.2)
P-value*	0.229		0.105		0.264		0.601		0.265		0.501	
Between group difference 95% CI	−3.6 to 14.7		−1.4 to 14.8		−5.1 to 18.3		−8.8 to 15.1		−4.4 to 15.8		−8.0 to 16.3	
12 weeks Mean (SE)	65.0 (2.7)	76.1 (2.6)	65.3 (2.6)	74.3 (2.6)	61.1 (3.8)	75.4 (3.3)	61.7 (3.6)	73.6 (3.6)	78.0 (3.3)	89.5 (2.1)	49.2 (3.6)	57.1 (4.8)
Change from baseline to 12 weeks Mean (SE)	0.6 (1.9)	10.0 (2.4)	−1.2 (2.2)	6.8 (2.3)	−1.9 (3.0)	11.6 (3.0)	−2.1 (3.3)	14.2 (3.3)	2.8 (2.5)	10.3 (3.0)	−2.2 (3.8)	6.0 (3.9)
P-value*	0.004		0.018		0.006		0.022		0.005		0.19	
95% CI	3.6–18.5		1.6–16.4		4.3–24.4		1.8–22.2		3.7–19.3		−4.0 to 19.8	
Waiting list control group eligible for intervention at this point (post 12 week)												
24 weeks Mean (SE)	74.6 (2.1)	72.8 (3.2)	74.7 (2.2)	73.6 (2.7)	71.9 (3.2)	70.0 (4.5)	72.7 (3.7)	70.5 (4.1)	88.8 (2.3)	86.3 (3.5)	58.0 (3.5)	54.9 (5.1)
Change from baseline to 24 weeks Mean (SE)	8.6 (2.5)	6.0 (2.9)	8.0 (2.6)	4.6 (2.6)	7.5 (3.6)	7.6 (3.7)	8.1 (2.9)	9.6 (4.1)	11.3 (2.9)	4.0 (3.7)	6.9 (4.2)	3.8 (5.5)

C = (Waiting List) Control Arm. I = Intervention. For maximum n values at baseline and follow-up please refer to Fig. 1. Bowel function I = bowel movements and use of facilities; Bowel function II = general bowel symptoms. Outcome and dimension scores have been converted to scores out of 100. A high score denotes higher QoL rating. Positive changes in values between time points indicate an improvement in QoL; Changes calculated using baseline data from only those cases that provided follow-up data. Reports comparisons of ITT analyses only. *Levene's test for equality significant (p = 0.005) so conservative estimate used.
*Univariate (between-group comparison) with 95% CI indicating the between group difference in change (Levene's test for equality significant (p=0.005) so conservative estimate used)..

3.1

Primary outcome

The primary outcome was difference between groups in score change for the patient reported MYMOP measure. As this measure allows patients to define the most problematic complaint, consideration of the reported issues is of value. Overall, responses coded subsequently as 'physical' (as opposed to mental) dominated the self-reported symptoms of participants; 'pain' comprised 24% of all symptom 1 and 2 responses; 'bowel habit' was presented as either symptom 1 or 2 in 17% of cases, other symptoms commonly reported included 'diarrhoea' (10%), 'cramp' (8%), and 'bloating' (7%). Activities made difficult by their condition were reported and subsequently coded as 'physical' (70% – e.g. exercising, working), 'social' (23% – e.g. socialising with friends), or 'mental' (6% – e.g. concentrating, sleeping).

Table 2 reports the median MYMOP item scores at baseline, 6-, 12- and 24-weeks. The intervention group demonstrated a significant improvement in all items of the MYMOP at 6 weeks (all at $p < 0.001$ with the exception of well-being, $p = 0.002$); improvements in all except 'well-being' were maintained at 12- ($p < 0.001$) and 24 weeks ($p = 0.002$).

Between-group differences (primary end-point) were significant for all items at both 6 and 12 weeks ($p \leq 0.001$) with the exception of "well-being" at 12 weeks ($p = 0.007$). At 24 weeks the waiting list control group (having then received the intervention) demonstrated significant improvements from baseline similar to those exhibited by the intervention group in week 6. At this point all between group differences were removed. After adjusting for age, gender and years since diagnosis, the difference-in-difference analysis between control and intervention from baseline, reported ITT effect sizes of 0.7 (95% CI 0.4–1.1) and 0.8 (95% CI 0.4–1.2) at 6 and 12 weeks, respectively. The adjusted PPA effect sizes presented an almost exact same pattern of results. Improvements greater than 0.5 units potentially confer notable benefit to the individual [46].

3.2

MYMOP: sub-group analysis

Table 3 reports MYMOP data according to disease type, irritable bowel syndrome (IBS) or inflammatory bowel disease (IBD). The intervention groups, both IBS and IBD demonstrated a significant improvement in MYMOP at 6 weeks maintained at 12, and 24 weeks.

Between-group differences were significant at both 6 and 12 weeks. At 24 weeks the waiting list control group (having now received the intervention) demonstrated significant improvements from baseline similar to those exhibited by the intervention group in week 6 in both IBS and IBD groups.

3.3

Secondary outcomes

3.3.1

Quality of life

Table 4 reports the mean QoL scores at baseline, 6-, 12- and 24- week follow-up for those with IBS. There were significant improvements from baseline overall scores for the intervention group, which were sustained at each follow-up point: 6 week (12.9 point improvement, 95% CI 8.5–17.3, $t = 5.874$, $p < 0.001$), 12 week (12.4 point improvement, 95% CI 7.0–17.8, $t = 4.666$, $p < 0.001$), and 24 week (13.8 point improvement 95% CI 8.2–19.4, $t = 4.982$, $p < 0.001$). After adjusting for age, gender and years since diagnosis, the difference-in-difference analysis between total scores for control and intervention participants from baseline reported ITT effect sizes of 10.7 (95% CI 5.3–16.1) and 7.6 (95% CI 0.9–14.2) at 6 and 12 weeks, respectively. The per protocol analysis effect sizes were larger: 12.6 (95% CI 6.7–18.4) and 10.4 (95% CI 3.6 – 17.1) at 6 and 12 weeks respectively.

Referring back to Table 4, all dimensions of QoL within the intervention group exhibited at least a 10-point improvement at week 12, maintained to week 24, with the only exceptions being 'body image' and 'relationships' which demonstrated smaller improvement. Improvement in the 'body image' dimension was not significant beyond week 6 using the criteria for significance pre-specified for sub-domains. The control group also demonstrated a moderate improvement of 5.1 points by week 12 (95% CI 1.1-9.0, $t = 2.581$, $p = 0.01$), although only the 'dysphoria' subscale demonstrated a significant improvement in this group (8.6 point improvement at week 12, 95% CI 3.2–14.0, $t = 3.199$, $p = 0.003$). Overall, improvements identified in the control group scores were consistently smaller than the intervention comparators.

Between-group differences were significant at week 6 for the overall score ($p = 0.001$) and dimensions of 'social reaction', 'food avoidance', 'interference with activity' and 'dysphoria' (all at $p< < 0.005$). Between-group differences were not demonstrated at week 12 for overall scores ($p = 0.013$) using the pre-specified threshold of significance or sub-scale scores ($p> > 0.005$), although all scores maintained improvement from baseline. At 24 week follow-up (post–treatment) the waiting list control group demonstrated a larger and significant improvement in overall QoL scores (95% CI 5.0–15.2, $t = 4.045$, $p < 0.001$).

When considering QoL in the IBD groups a similar pattern emerged (Table 5). The intervention group demonstrated significant improvement in overall QoL score at week 6 (95% CI = 1.9–12.1, $t = 2.79$, $p = 0.008$) and week 12 (95% CI = 5.2–14.9, $t = 4.166$, $p <0.001$), but did not maintain improvement from baseline at week 24 (95% CI = 0.2–11.9, $t = 2.098$, $p = 0.044$). Change in specific dimension scores indicated that social function and bowel function may have driven this change, as they both present score improvements of more than 10 points. As observed in the IBS group, the IBD control group demonstrated a marginal increase in overall scores at 12 weeks (0.6 point

improvement), however this was not considered a significant change (CI −3.4 to 4.5, t = 0.290, p = 0.773). No significant changes in subscale scores were observed either. The between-group differences in overall scores were significant at week 12 (p = 0.004) only.

After adjusting for age, gender and years since diagnosis, the difference-in-difference analysis between total scores for control and intervention participants from baseline reported ITT effect sizes of 5.8 (95% CI 0.2–11.4) and 10.1 (95% CI 4.3–15.9) at 6 and 12 weeks, respectively. The adjusted PPA effect sizes presented a similar pattern of results.

3.3.2

Severity of symptoms

Table 6 reports the different symptom severity measures for each disease type at baseline, 6-, 12- and 24-week follow-up. For IBS groups improvement in severity scores was significantly different between the intervention group and the waiting list controls at week 6 (1.8 point improvement in controls versus 6.1 in intervention, p < 0.001). This seems primarily attributable to the difference in F scores at this point. Between-group differences were also observed at week 12 but to a lesser extent (total score change 3.0 control versus 5.5 intervention, p = 0.018). After adjusting for age, gender and years since diagnosis, the difference-in-difference analysis between control and intervention total scores from baseline reported ITT differences of 4.3 (95% CI 1.9–6.9) and 2.8 (95% CI −0.1 to 5.7) at 6 and 12 weeks, respectively. The adjusted PPA effect sizes presented a similar pattern of results. In the light of baseline scores of around 23 units this is likely to reflect a clinically determinable effect.

Table 6

Symptom severity outcome scores at baseline and 6-, 12-, and 24 weeks.

Table 6

	Irritable Bowel Syndrome								Ulcerative Colitis		Crohn's Disease	
	Total		Pain (subscale)		Constipation (subscale)		Diarrhoea (subscale)		Total		Total	
	C	I	C	I	C	I	C	I	C	I	C	I
Baseline Mean (SE)	23.6 (1.0)	23.1 (1.1)	8.7 (0.5)	8.0 (0.5)	5.3 (0.6)	5.4 (0.5)	9.7 (0.6)	9.8 (0.8)	4.7 (0.5)	4.3 (0.5)	6.7 (1.1)	8.5 (1.6)
Week 6 Mean (SE)	22.1 (1.0)	15.9 (1.1)	8.4 (0.6)	5.5 (0.4)	5.7 (0.6)	4.6 (0.6)	8.1 (0.8)	5.7 (0.6)	4.4 (0.5)	3.8 (0.5)	5.5 (1.1)	7.9 (2.3)
Change from baseline to 6 weeks Mean (SE)	1.8 (0.9)	6.1 (1.0)	0.7 (0.4)	2.0 (0.4)	−0.2 (0.5)	0.8 (0.4)	1.3 (0.2)	3.3 (2.1)	0.1 (0.4)	0.4 (0.4)	0.9 (0.8)	0.8 (0.7)
P-value*	<0.001		<0.001		0.229		0.018		0.410		0.366	
Between group difference (95% CI)	−9.1 to −3.2		−4.2 to −1.5		−2.7 to 0.7		−4.4 to −0.4		−2.2 to 0.9		−2.8 to 7.6	
Week 12 Mean (SE)	20.8 (1.2)	16.5 (1.3)	7.5 (0.6)	5.9 (0.6)	5.4 (0.6)	4.6 (0.6)	7.8 (0.8)	6.1 (0.7)	4.5 (0.5)	3.1 (0.5)	6.6 (1.0)	7.0 (1.3)
Change from baseline to 12 weeks	3.0 (1.0)	5.5 (1.1)	1.4 (0.5)	1.4 (0.4)	0.4 (0.5)	1.1 (0.5)	1.3 (0.5)	3.0 (0.5)	0.2 (0.3)	0.7 (0.4)	−0.4 (1.0)	1.9 (1.7)

	Irritable Bowel Syndrome								Ulcerative Colitis		Crohn's Disease	
	Total		Pain (subscale)		Constipation (subscale)		Diarrhoea (subscale)		Total		Total	
	C	I	C	I	C	I	C	I	C	I	C	I
Mean (SE)												
P-value*	0.018		0.048		0.312		0.093		0.046		0.808	
CI	−7.7 to −0.7		−3.3 to 0.0		−2.5 to 0.8		−3.7 to 0.3		−2.9 to 0.0		−3.0 to 3.8	
Waiting list control group eligible for intervention at this point (post 12 week)												
Week 24	19.0 (1.5)	17.8 (1.4)	6.8 (0.6)	6.0 (0.6)	5.3 (0.7)	4.6 (0.7)	6.8 (0.9)	7.2 (0.8)	3.5 (0.5)	3.4 (0.5)	4.3 (1.4)	4.4 (1.6)
Mean (SE)												
Change from baseline to 24 weeks	4.4 (1.5)	4.1 (1.2)	1.8 (0.7)	1.1 (0.5)	0.5 (0.7)	0.7 (0.6)	2.1 (0.7)	2.2 (0.6)	0.7 (0.5)	0.4 (0.3)	0.5 (0.8)	1.0 (1.6)
Mean (SE)												

C = (Waiting List) Control Arm. I = Intervention. For maximum n values at baseline and follow-up please refer to Fig. 1. Decrease in scores indicates improvement in severity. Score ranges for outcome measures: IBS total score (0–55): IBS pain (0–25), IBS constipation (0–15), IBS diarrhoea (0–15); UC total (0–19); CD total (0–13 +). Changes calculated using baseline data from only those cases that provided follow-up data. Reports comparisons of ITT analyses only.

Symptom severity scores in those with IBD showed no significant between-group differences in scores at 6- or 12- weeks despite a consistent trend towards greater improvement in the intervention group. After adjusting for age, gender and years since diagnosis, the difference-in-difference analysis between control and intervention total scores from baseline reported ITT effect sizes of 0.3 (−0.8 to 1.3 at 95% CI) and 0.6 (−0.5 to 1.6 at 95% CI) at 6 and 12 weeks, respectively. The adjusted PPA effect sizes presented a similar pattern of results. Due to the relatively small numbers within the Crohn's disease group no further analysis is reported here.

4

DISCUSSIONiscussion

This is the first randomised controlled trial to examine the benefits of healing therapy as an adjunct to conventional management of individuals with IBS and IBD. The results demonstrate that when used alongside standard medical care healing therapy confers additional benefit. Benefits observed in our IBS cohort in terms of both symptom reduction and QoL improvement were significant, consistent and of size likely to be associated with 'clinical benefit'. Observations within the IBD cohort suggested benefit in some sub-domains but lacked the strength of association or consistency over measures and time points observed in the IBS group.

QoL was considerably enhanced in the IBS intervention group with improvements in emotional states, socialization, and activity levels which were maintained up to week 24 and were significantly different from controls. Parallel to observations made in the MYMOP data, there was a meaningful improvement in the QoL scores for the control group once they also received the intervention. QoL improvements in the IBD group were noted but these did not differ between the intervention and control groups.

When evaluated collectively using the MYMOP, all symptom and activity measures (except for well-being) showed improvements which were maintained up to week 24, suggesting the possibility of longer term benefits beyond the period of therapy. Changes in scores were of a size with the potential to result in notable improvements to the patient. Failure to demonstrate benefits to general well-being despite improved symptoms and activity may be attributed to other factors which have greater impact on well-being than symptoms and activity or could represent a time lag factor whereby general perceptions of well-being are accrued after a period of reduced symptoms. Improvements in MYMOP scores were seen in both IBS and IBD groups.

In this clinical trial we have studied two distinct gastrointestinal syndromes with similar symptoms yet contrasting aetiologies, IBS, a functional syndrome and IBD a bona fide organic disease. We have observed that healing therapy is beneficial both in terms of improvement in patient perception of disease impact (determined by MYMOP) which was our pre-specified primary outcome. In IBS this MYMOP change appeared related to both improved QoL and symptom improvement. In IBD the MYMOP improvement is less clearly defined as neither QoL or symptom scores differed between intervention and control groups. This study does not address the mechanism of this effect, nor the magnitude of the placebo effect. Use of "sham" therapy would not provide adequate placebo control because of the impact of the 'actor' having an unintended therapeutic effect on participants through such a mechanism as unintended channelling of energy. Small improvements observed in the control group during the waiting period could be explained as a Hawthorne effect. The control group continued to have significantly poorer profile scores throughout this period which subsequently improved once they received the intervention. Per protocol analyses suggested that greater benefit was associated with compliance further supporting the observed findings.

As a whole, physical symptoms dominated, with pain being the most common, experienced by nearly a quarter, and around one-fifth had difficulties with bowel habit. Condition-specific data collected from IBS-QOL and IBDQ questionnaires showed that symptom severity score improvements in IBS groups were largely a result of improvement in pain levels. Variation in levels of symptom benefit reported between IBS and IBD may be explained by the dissimilar disease pattern between the two conditions. It is well known that in IBS added to the biological factor, there is a strong interplay of psychological and social factors [47,48] that influence severity. These findings may suggest that conditions linked to functional disorders could accrue greater benefit from healing therapy. Whether the differential impact of healing observed in this study is an artefact of a greater placebo response in individuals with functional disorders will require further study, although we would argue that the size of the improvement in this group would make healing a useful therapeutic approach irrespective of mechanism of action. Our intention was not to attempt to define mode of action but to explore from a pragmatic perspective whether the addition of healing therapy could accrue patient benefit.

Previous studies on healing therapy (includes Healing Therapy, Therapeutic Touch and Reiki) have been undertaken on a range of conditions and symptoms, including cancer, chronic pain conditions, anxiety, wound healing and HIV, comparing its efficacy with other complementary therapies as well as standard medical care. Results from this study are analogous to the conclusions made by these previous studies which generally support the effectiveness of healing therapy to reduce pain, anxiety and improved QoL [29,4950],50].

We found no evidence of harm from healing therapy; many patients found it an interesting and enjoyable experience and qualitative patient experience data has been collected for further analysis. Further cost-effectiveness evaluation is required before determining the role healing therapy may play in resource restricted health services. Patients with IBS and IBD seen in secondary care, who remain symptomatic despite the best medical care, should be considered for Healing Therapy where this is available with the understanding that benefit is likely to be greater in individuals with IBS. It is of note however that participants in this trial were all recruited from secondary care and therefore the IBS represented is atypical (having failed primary care management), therefore additional treatment strategies for this difficult to manage sub-group of patients are highly desirable. Conventional drugs are aimed at suppressing symptoms, but we are now much more aware that symptom management is not limited only to the prescription of drugs [49]. This study has demonstrated that clinically there is benefit to be gained from inclusion of healing in the management of IBS which has not responded to conventional management. Research in IBS also recognises that due to its non homogeneous population not all treatments may be suitable for all patients [51], something which has been observed in this study and could be a consideration for future studies.

4.1

Limitations

Generalisability of the study is limited to the self-selective nature of the participants into the trial, amongst who may be patients that already have an affinity for complementary therapies, or have a previous positive experience of healing or other similar type of therapy. Admittedly, both of these offer a potential bias towards therapeutic gain. However, findings from our associated qualitative [37] work reveal that patients who volunteered for the trial were not necessarily non-sceptics of the complementary therapy approach, and anecdotal findings also suggest that many had not tried such therapies before. This study is also subject to biases inherent in trials where blinding has not been achieved. The decision to utilise a pragmatic trial design with waiting list control was made after careful consideration. It has been suggested that

trials which use a ‘sham’ therapist are subject to the impact of the ‘actor’ having an unintended therapeutic effect on participants and this along with ethical considerations drove this decision. Furthermore we wished only to determine whether adding healing to usual care of patients would offer improvements rather than demonstrate which of the component parts of a complex intervention offered benefit. However there remains the possibility that benefit in the healing arms was entirely attributable to a placebo effect. There is further possibility that waiting list patients who were aware of the nature of the intervention offered may have demonstrated a nocebo response. It has been indicated in the context of trials used in psychological and behavioural research that patients on the waiting control trial list: “appear to improve less (or not at all) than would be expected for people who are concerned about their behaviour and who are taking steps to change” [52] and it is also therefore a possibility that those in the waiting list group deferred taking personal action to alleviate symptoms. Interestingly in the current study there was a consistent tendency towards improvement in the control group. Such a finding is not unusual and is typically explained by regression to the mean or the accepted positive impacts of trial participation. This observation does perhaps support the fact that simple provision of attention and interest in symptoms and illness experiences has a positive impact. The fact that improvements in IBS were not fully replicated in IBD patients may also hint towards a placebo element to the observed effect although this in no way discredits the findings of this trial. The dissimilarities between UC and CD increase the challenges to study these conditions collectively under the umbrella of IBD and the small number of patients with CD in this study would also skew the overall picture for IBD suggesting different results may be demonstrated if each of these groups is studied separately with an adequate sample size. Whilst the decision to include CD after commencement of the trial to ensure IBD target numbers were achieved we acknowledge that this more heterogeneous group may have reduced the ability to identify benefits within an IBD sub-group.

5 Conclusion

This pragmatic trial demonstrates that patient benefit is accrued through the addition of healing therapy to conventional management of both IBS and IBD. The greatest benefit was observed in individuals with IBS where differences which would confer a clinically determinable benefit were observed. The benefit observed may at least be, in part, a placebo effect although the size of benefits observed suggests an alternative mechanism and the value of any mechanism should arguably not be discounted where it confers symptomatic relief.

COMPETING INTERESTSNone.FUNDINGompeting interests
None.
Funding
This study was funded by the Big Lottery.
RL, LR and SS conceived and designed study, were involved in data interpretation and manuscript writing. TK was responsible for data collection, analysis and interpretation and manuscript writing. SE was involved in conception of study and manuscript review. AS and PS were involved in interpretation of data and manuscript writing. MH was involved in analysis of data.
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Acknowledgements
We would like to acknowledge the participants of this trial in addition to hospital staff and healers who contributed to the study.

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